

|                  |   |
|------------------|---|
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| Document #       | DKPI-09233-001 1.5 DRAFT 2024-05-16   |
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|------------|---|



 The twiist automated insulin delivery system is Magnetic Resonance Unsafe. Disconnect the pump before entering an MRI scan room. Do not bring your iPhone or pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner can cause the pump and iPhone to move or lead to electric shocks and may result in severe injury.

**Detach the Magnetic Resonance Unsafe card and keep with you while using the system.**



#### **Magnetic Resonance Unsafe**

This person has a twiist automated insulin delivery system. Do not enter an MRI scanner room or a Magnetic Resonance system. Doing so may result in injury.

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Keep this card with you while using the system.



#### **Magnetic Resonance Unsafe**

This person has a twiist automated insulin delivery system. Do not enter an MRI scanner room or a Magnetic Resonance system. Doing so may result in injury.

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Keep this card with you while using the system.



# Emergency Contact Information

Name

Phone Number

Healthcare Provider

Certified twiist Pump Trainer

Pharmacy

Notes



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# Conventions

These tables describe the conventions used in this document.

## Formatting Conventions

| Convention  | Description   |
|-------------|---|
| Blue Text   | Blue text provides a cross-reference to content in another section within this user guide.  |
| Bold Text   | Bold text is used to emphasize buttons within the twiist app or on the pump the operator interacts with.  |
| Italic Text | Italic text is used to emphasize: <ul style="list-style-type: none"><li>• Words or phrases that appear on the twiist app screen.</li><li>• Parts or features of the system.</li><li>• Sounds played by the system.</li><li>• Headings</li></ul> |

## Terminology

| Term   | Description   |
|--------|---|
| Button | Refers to a physical button or a software button displayed on a touchscreen.  |
| Icon   | A symbol displayed within the twiist app indicating an option or information, or a symbol on your pump or system packaging. |
| Keypad | Used to enter alpha or numeric values into the twiist app.  |
| Picker | A tool displayed within the twiist app for selecting a value. Swipe up or down on the touchscreen to select a value.        |
| Press  | Press down on a physical button with your fingertip.  |

| <b>Term</b>          | <b>Description</b>   |
|----------------------|--|
| Press/Touch and Hold | Continue to touch an area of the touchscreen or keep pressing a physical button until the action is complete.                    |
| Select               | The act of choosing from a list of options on the touchscreen.   |
| Swipe                | Place your fingertip on the touchscreen and slide your finger in a specified direction to activate a function or select a value. |
| Tap                  | Quickly and gently touch the screen with your fingertip.   |
| Touchscreen          | The display device which allows you to interact with the twist app on your iPhone.   |

# Symbols

The following symbols are used within this User Guide.

| Symbol  | Definition   |
|---|--|
|  | Read manufacturer's instructions prior to use.   |
|  | Identifies an important note about the use of the system.  |
|  | Caution - Used to notify the caregiver or patient of potential hazards. Obey all safety messages that follow this symbol.                          |
|  | Warning - Used to notify the caregiver or patient of potential hazards. Obey all safety messages that follow this symbol to avoid possible injury. |

| Symbol   | Definition   |
|--|--|
|  | Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment. |

## Explanation of Symbols

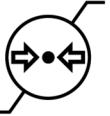
Labeling symbols are displayed on your pump, supplies, and packaging. These symbols provide information necessary to use the system and supplies safely.

| Symbol  | Definition  |
|---|---|
|  | Indicates a potential hazard. Obey all safety messages that follow this symbol. |
|  | Prescription use only   |
|  | Single use only   |
|  | Material may be recycled  |

| Symbol   | Definition          |
|--|---------------------|
|  | Manufacturer        |
|  | Date of Manufacture |
|  | Expiration date     |
|  | Lot code            |
|  | Catalog number      |
|  | Serial number       |

| Symbol            | Definition                       |
|-------------------|----------------------------------|
|                   | Do not use if package is damaged |
| <b>STERILE</b>    | Sterile                          |
| <b>STERILE EO</b> | Sterilized using ethylene oxide  |
| <b>STERILE R</b>  | Sterilized using irradiation     |
|                   | Non-pyrogenic                    |
|                   | Keep dry                         |
|                   | Type BF Applied Part             |

| Symbol | Definition  |
|--------|---|
|        | Direct Current required   |
|        | Recycle lithium-ion batteries   |
|        | Separate collection for electrical and electronic equipment waste.      |
|        | Magnetic Resonance Unsafe – Items should not enter an MRI scanner room. |
|        | Temperature limit   |

| Symbol  | Definition                      |
|---|---------------------------------|
|  | Humidity limitation             |
|  | Atmospheric pressure limitation |

# System Description

The twiist™ Automated Insulin Delivery (AID) System powered by Tidepool® consists of the twiist pump, a twiist 3 mL (300 units) cassette, the twiist app, and a compatible infusion set for the continuous subcutaneous (under the skin) delivery of insulin, at set and variable rates, for the management of diabetes.

The twiist automated insulin delivery system includes twiist™ Loop powered by Tidepool®, an optional automated insulin dosing system, when used with a compatible integrated continuous glucose monitor (iCGM).

The twiist automated insulin delivery system is intended for single-patient use and requires a prescription.

The twiist pump and app, Loop, and a compatible iCGM may be referred to as the twiist automated insulin delivery system or twiist AID system.

The twiist app provides a means of programming and controlling the pump and viewing historical data.

The twiist automated insulin delivery system delivers basal insulin, at a programmed rate, and bolus insulin deliveries to cover meals or lower blood glucose.

You can choose to use an *Apple Watch* with the twiist app.

This optional component provides a discreet way to view your sensor glucose and insulin information, enter carbs, and deliver a bolus of insulin.



The twiist pump, app, and iCGM communicate via Bluetooth. Basal deliveries are made even when the twiist pump and app are not communicating.

When your iPhone is on and within Bluetooth range of the pump, the twiist app will display insulin dosing and optional glucose information.

The twiist pump contains volume measurement hardware, pump actuation hardware, and electronics. The pump is powered by a rechargeable battery designed specifically for the system.

Each single-use, disposable cassette can be filled with up to 300 Units (3 mL) of U-100 Humalog (insulin lispro) or Novolog (insulin aspart) and attaches to the pump. The cassette includes a luer connector, and chambers for storing, pumping, and measuring insulin, as well as valves used to control the flow of insulin.

The pump and cassette chambers actively draw up to 0.002 mL aliquots of insulin from the storage chamber in the cassette, measure the volume of each aliquot, and then deliver these aliquots into the patient. These individual measurements are used to accurately deliver insulin and detect occlusions.

Insulin is infused through an attached infusion set. Cassettes and infusion sets are replaced every 48-72 hours.

The twiist system can be used for basal and bolus deliveries whether a CGM is in use or not. If a CGM is not in use, CGM readings will not be displayed by the twiist app. Loop cannot be enabled when a CGM is not in use.

The CGM and pump communicate via Bluetooth. The twiist app displays CGM readings, a rate of change indicator, and a glucose trend graph.

You must be trained by a healthcare provider before using the twiist automated insulin delivery system. If you have not received training, contact Sequel.

# What Is Loop?

The twiist automated insulin delivery system includes Loop for optional automated basal insulin dosing. It works differently than your twiist pump does by itself.

Some features of the twiist automated insulin delivery system may work differently or be unavailable when *Loop* automation is off.

When *Loop* is on, the twiist AID system makes a prediction about your future glucose by looking at:

- Your settings
- Your CGM readings
- Your recent insulin deliveries
- Your recent carb entries



The twiist AID system adjusts your basal insulin by pulling together information about your glucose from your CGM, insulin from your twiist pump, and details you enter about carbs you eat, plans for exercise, and the glucose correction range you are aiming for.

Your insulin delivery is adjusted in the background to reduce high and low glucose and work to keep you in your *Correction Range*.

The twiist AID system makes a calculation as often as every 5 minutes. This 5 minute cycle is called a *Loop*.



Using the twiist AID system with *Loop* on is not a substitute for good diabetes management.

Keep the twiist AID system informed about where you would like your glucose to be by setting your correction range.

The twiist app allows you to let the system know to work a little harder to lower your glucose before a meal. This allows *Loop* to start adjusting for carbs you plan to eat before you consume them.

Let the twiist AID system know you want your glucose to remain elevated while you exercise or to slow down a rapidly falling glucose.



The twiist AID system can continue to make adjustments to your basal whether or not your twiist pump is in communication with the twiist app.

Use twiist with *Loop* off when:

- You do not have an active CGM.
- You may want to take full manual control of your insulin dosing decisions.

**⚠** Do not set glucose safety limit, correction range, pre-meal range, workout range, carb ratios, basal rates, insulin sensitivities, or insulin model without direction from your healthcare provider. Incorrect settings may lead to low or high blood glucose.

## About this User Guide

This user guide provides important information about how to operate the twiist automated insulin delivery system, including step-by-step instructions to setup, manage, and care for the system.

Important warnings and cautions related to safe operation and technical information are also included in this user guide.

 Values displayed in this user guide are for demonstrating the use of the system features and should not be used for your treatment needs.

## Indications For Use

The twiist system is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, ages six and above. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The twiist system is intended for single patient, home use and requires a prescription.

## *Loop Indications for Use*

Loop is intended for use with compatible integrated continuous glucose monitors (iCGM) and the twiist alternate controller enabled (ACE) insulin infusion pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also recommend, and with the user's confirmation, deliver correction boluses when glucose values are predicted to exceed user configurable thresholds.

Loop is intended for the management of type 1 diabetes mellitus in persons six years of age and greater, and is intended for single-patient use.

The twiist automated insulin delivery system is for prescription use only .

## *Bolus Calculator Indications For Use*

The simple bolus calculator, available when *Loop* is off, is indicated for use for aiding the user in determining the bolus insulin dosage for management of diabetes mellitus based on consumed carbohydrates, operator-entered blood glucose, insulin sensitivity, insulin to carbohydrate ratio, correction range, and current active insulin.

## Contraindications

The twiist automated insulin delivery system is not intended for anyone unable or unwilling to:

- Test blood glucose (BG) levels as recommended by their healthcare provider.
- Maintain sufficient diabetes self-care skills.
- See their healthcare provider regularly.
- Demonstrate adequate carbohydrate-counting skills (preferred, not required).

The user must not:

- Have difficulty seeing.
- Have difficulty hearing.
- Have deficient cognitive capabilities.
- Have physical impairments which would make operating the pump or iPhone difficult.

# Compatibility

## Insulin

The twiist automated insulin delivery system is designed to use fast-acting U-100 insulin. The following U-100 fast-acting insulin analogs have been tested and found to be safe for use in the system:

- Humalog (insulin lispro)
- Novolog (insulin aspart)

Humalog (insulin lispro) and Novolog (insulin aspart) were found to be compatible with the twiist automated insulin delivery system for 72 hours (3 days) maximum use time.

## Cassettes

The twiist automated insulin delivery system is compatible with one cassette: The twiist cassette. This cassette was found to be compatible with the twiist automated insulin delivery system for 72 hours (3 days) maximum use times when using Humalog (insulin lispro) or Novolog (insulin aspart).

## Infusion Sets

The twiist automated insulin delivery system is compatible with the following infusion sets:

- Medtronic MiniMed Quick-set Infusion Set:
  - 43 inch MMT-390
  - 42 inch MMT-391
  - 23 inch MMT-392
  - 23 inch MMT-393
- Medtronic MiniMed Silhouette Infusion Set:

- 23 inch MMT-373
- Unomedical Comfort:
  - 23 inch
- Smiths Medical Cleo 90 Infusion Set:
  - 24 inch 21-7220-24
  - 31 inch 21-7221-24
  - 42 inch 21-7222-24
  - 24 inch 21-7230-24
  - 31 inch 21-7231-24
  - 42 inch 21-7232-24

Replace your infusion set every 48-72 hours, or per your healthcare provider instructions.

## iCGMs

The twiist automated insulin delivery system is compatible with the following iCGMs:

- Dexcom G6®

For information about Dexcom G6 product specifications and performance characteristics, see the user guide provided by the manufacturer. Dexcom G6 sensors and transmitters are sold and shipped separately.

 A Dexcom G6 CGM can either be paired to the twiist automated insulin delivery system or the Dexcom G6 receiver.

Use the Dexcom G6 app on your iPhone when connecting your Dexcom G6 CGM with the twiist automated insulin delivery system.

 Product information for the Dexcom G6 CGM System includes important information on how to use the Dexcom G6 CGM (including sensor glucose readings, trend graph, trend arrow, and alarm/alerts) to make treatment decisions.

Ensure that you have reviewed this information and discussed it with your healthcare provider, who can guide you in correctly using your Dexcom G6 CGM when making treatment decisions.

## iPhone Compatibility

The twiist app requires an iPhone with version 16 or greater of the *Apple iPhone* operating system (iOS).

 Do not run the twiist app on an iPhone with unauthorized modifications. In order for the twiist app to work properly, it must be used on a compatible iPhone that does not have a modified operating system (jailbroken device).

 Do not install apps on your iPhone from untrusted sources. Installing apps from any source other than the *App Store* on your iPhone running the twiist app may put you at risk of unintentionally installing malware, which may impact the use of the twiist app. Only install apps from the *App Store*. Malware, or malicious software from unknown sources, is designed to damage your device and/or read your private information. The most common method for spreading malware is the use of unknown apps and unknown downloads. Malware can prevent the twiist app from functioning as intended, causing over-delivery or under-delivery of insulin, which may lead to high or low glucose.

If you believe you have malware on your iPhone, discontinue use of the twiist app and use an alternate means of insulin delivery until you are able to resolve. If you have any apps installed from unknown sources, delete the app, restore your iPhone to factory default settings and contact *Customer Support*.

## Apple Watch Compatibility

The twiist app is compatible with all released versions of the Apple Watch and Apple Watch OS 4.1 and newer.

## Important User Information

Read all instructions in this user guide, and the instructions from your infusion set manufacturer before use of this system.

Throughout this user guide, the patient is the intended operator.

The following items must be understood prior to using the twiist automated insulin delivery system:

- The operator is able to program the system with appropriate basal rates.
- The operator is able to adjust the basal rates as instructed.
- The operator is able to deliver a bolus as instructed.
- The operator understands only approved cassettes and infusion sets may be used with the system.

- The operator is able to execute the proper procedure for changing a cassette.
- The operator is able to execute the proper procedure for resolving an alarm.

Test blood glucose and take appropriate corrective action as advised by your healthcare provider in the event blood glucose is too high or low.

If you are a new CGM user, or your symptoms do not match your CGM reading, use a BG meter to check your glucose values.

If you have read this user guide and have questions, contact Sequel customer support, available 24 hours a day, 7 days a week. *See "Customer Support" on page 195.*

## Important Information about Your iPhone

Your iPhone includes features that may impact the use of the twiist automated insulin delivery system, including settings that may prevent alarm and alert notifications from appearing or providing audio notification or vibration.

If an alarm occurs, the pump will provide audio notification.

If you use *Focus* features such as *Do Not Disturb*, make sure to allow notifications from the twiist app.

When using *Screen Time*, make sure the twiist app is configured as **Always Allowed**.

If you use the iPhone *Scheduled Summary* feature for notifications, do not add the twiist app to the *Summary* list. *Scheduled Summary* may delay the delivery of *Alert* or *Alarm* notifications.

Take care when using *Accessibility* settings such as *Zoom*. Using the *Zoom* feature will prevent you from seeing the entire application screen at the same time.

Accessibility settings such as *Bold Text*, *Large Text*, or contrast settings such as *Increase Contrast*, *Smart Invert*, or *Classic Invert* will change the way information appears within the twiist app.

## Important Pediatric User Information

It is the responsibility of the healthcare provider and caregiver to determine if the patient is a good candidate for treatment with the twiist automated insulin delivery system.

Review your device settings and features like *One-Button Bolus* to make sure they are configured appropriately. Younger users may press the pump button leading to unintentional delivery of insulin.

Children may dislodge their infusion site more frequently. Make sure infusion set tubing is secure.

## Emergency Supplies

Always have emergency supplies available. Talk to your healthcare provider about what you should keep in your emergency supplies in addition to:

- Blood glucose monitoring supplies
- Fast-acting glucose tablets
- Unopened sterile, single-use, 3 mL syringe and 26 gauge x 1/2 inch needle
- Unopened cassette
- Spare insulin
- Unopened infusion set
- Alcohol wipes

## Working with your Healthcare Provider

Clinical language contained within this user guide is used based on the assumption that you have been educated by your healthcare provider on terminology that applies to your diabetes management. Consult with your healthcare provider before using the twiist automated insulin delivery system to determine which features are appropriate for your use. Only your healthcare provider should assist with the adjustment of your therapy settings.

# Important Safety Information

The following section includes important safety information related to your twiist automated insulin delivery system. Additional and repeated warnings and

cautions (  or  ) appear throughout this user guide where appropriate.

## Warnings

Warnings (  ) provide information about detailed situations and the possible result of not following the guidance which could lead to death or serious injury.

 Do not use the twiist automated insulin delivery system before reading this user guide. Failure to follow the instructions provided in this user guide may result in over or under delivery of insulin, which may lead to low or high blood glucose. If you have questions about system use, contact your healthcare provider or Sequel customer support. *See "Customer Support" on page 195.*

 When Loop is on, do not modify a bolus to be greater than the recommended value. Increasing the bolus can lead to increased risk of low blood glucose.

 Do not use the twiist automated insulin delivery system if you have not received training on appropriate use by a certified twiist trainer. Discuss your individual training needs with your healthcare provider. Failure to receive the appropriate training could result in serious injury or death.

 The twiist automated insulin delivery system is not recommended for use by an operator with poor vision. Poor vision may prevent the correct reading of information displayed within the twiist app and may lead to harm.

**⚠** If the twiist automated insulin delivery system fails to work as described within this user guide, stop using the system and switch to your backup insulin therapy. Using the system when it is not working as described within this user guide may lead to harm.

**⚠** Only use fast-acting U-100 Humalog (insulin lispro) or Novolog (insulin aspart). Use of other concentrations may lead to insulin delivery errors that may lead to low or high blood glucose.

**⚠** Do not set glucose safety limit, correction range, pre-meal range, workout range, carb ratios, basal rates, insulin model, or insulin sensitivities without direction from your healthcare provider. Incorrect settings may lead to low or high blood glucose.

**⚠** Always have a backup insulin therapy plan ready. A backup plan is needed if insulin delivery is stopped unexpectedly or the pump fails. Failure to have a backup insulin therapy plan may lead to delays of insulin delivery. Extended delay of insulin delivery may cause high blood glucose or diabetic ketoacidosis (DKA).

**⚠** Do not use cassettes, infusion sets, needles, or syringes that are past the expiration date on their packages. Using expired sterile components may lead to infection.

**⚠** Only use cassettes and infusion sets listed in the user guide. Failure to do so may affect accuracy or blockage detection which may lead to over or under delivery and cause low or high blood glucose.

**⚠** Do not use cassettes, infusion sets, needles, or syringes from previously opened or damaged sterile packaging. Use of disposable components from previously opened or damaged sterile packaging may lead to infection.

**⚠** Do not use damaged cassettes or infusion sets. Using damaged cassettes or infusion sets may result in start-up failures, interruptions in therapy, or topical exposure to insulin.

**⚠** Always rotate insulin infusion sites to help prevent infusion site complications like scar tissue and infection. Rotating insulin infusion sites reduces the risk of scarring. Using a site with scar tissue can lead to problems with insulin absorption or blockages that may lead to high blood glucose.

⚠ Always follow your infusion set manufacturer's instructions for infusion site insertion and care. Failure to do so may result in over or under delivery of insulin or infection.

⚠ Make sure to prime the infusion set tubing. Failure to prime the infusion set tubing may lead to a delay in the delivery of insulin resulting in high blood glucose or cause a delivery error.

⚠ Do not fill the cassette with cold insulin. Filling the cassette with cold insulin may result in air bubbles forming in your cassette or infusion set tubing that may result in delivery errors that may lead to harm. Allow insulin to adjust to room temperature before filling the cassette.

⚠ Do not fill or prime the cassette and infusion set tubing while connected to your infusion site. Connecting the infusion set tubing during filling and priming may lead to the unintended over delivery of insulin which may result in low blood glucose.

⚠ Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery error and lead to harm.

⚠ Do not connect a filled cassette and infusion set tubing to your infusion site if the cassette is not attached to the pump. Connecting the filled cassette and infusion set tubing to your infusion site before connecting the cassette to the pump may lead to unintended insulin delivery leading to low blood glucose.

⚠ Do not connect infusion set tubing to your infusion site before the pump completes self-test. Connecting infusion set tubing to your infusion site during self-test may lead to unintended delivery of insulin, which may lead to low blood glucose.

**⚠** Damaging the inside of the pump or cassette which are exposed while changing the cassette or battery may affect pumping accuracy which may increase or decrease delivery and lead to low or high blood glucose.

**⚠** Dirt, lubricants, or liquids may contaminate the inside of the pump while it is detached from the cassette. Contamination may affect pumping accuracy, which may increase or decrease insulin delivery causing low or high blood glucose.

**⚠** Do not fill a cassette before you plan to use it. Filling a cassette before you plan to use it may result in spoilage or a change to the potency or purity of insulin, which may lead to harm.

**⚠** Before removing the cassette from your pump, disconnect the infusion set tubing from your infusion site. Leaving the infusion set tubing connected may result in unintended delivery, leading to low blood glucose.

**⚠** Do not leave the cassette and infusion set tubing connected to your infusion site when investigating or resolving a *Line Blocked* alarm. Leaving the infusion set tubing connected during a *Line Blocked* alarm may lead to unintended delivery of insulin, which may cause low blood glucose.

**⚠** Pets may damage your infusion set tubing while sleeping which may lead to an interruption of insulin delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.

**⚠** Only use the provided wall power adapter and charging cables. Use of another wall power adapter or cables could damage the system or result in fire or burns.

**⚠** Do not use batteries or battery chargers that were not supplied with the system. Use of batteries and battery chargers that did not come with the system may lead to unsafe operation which may lead to harm.

**⚠** The system may affect nearby electrical devices (such as antennas or radios), including medical ones. This could cause these devices not to work properly or stop working. Keep the pump and pump battery charger away from these devices.

⚠ Retail anti-theft detectors may affect pump accuracy or trigger an alarm. Walk through retail anti-theft detectors at a normal pace, but avoid standing in them.

⚠ Portable RF communications equipment including antenna cables and external antennas may affect the communication between the twiist pump and app, or interrupt operation of the pump. Keep the pump at least 12 inches (30 cm) away from these items.

⚠ Metal detectors may affect pump accuracy or trigger an alarm. Handheld or walk through metal detectors may be used near the system, but prolonged exposure to them should be avoided.

⚠ Avoid exposing your pump to temperatures below 41 °F (5 °C) or above 104 °F (40 °C). When in cold temperatures, the pump should be worn close to the body and covered in warm clothing. When in warm temperatures, take measures to keep the pump cool.

⚠ Do not allow children to ingest small parts, such as the pump batteries. Small parts could pose a choking hazard. If swallowed, these small parts may cause internal injury or infection.

⚠ Exposed infusion set tubing could pose a choking hazard. Keep exposed infusion set tubing out of the reach of unsupervised children.

⚠ Do not perform troubleshooting steps while the pump is connected to your infusion site. Performing troubleshooting steps while the pump is connected to your infusion site may lead to unintended delivery of insulin, which may lead to low blood glucose.

⚠ A passcode must be enabled on your iPhone to use the twiist app. Your iPhone passcode prevents unauthorized changes to your therapy settings or insulin delivery, which may lead to low or high blood glucose. Your passcode should not be shared with unauthorized operators.

**⚠** For patients who do not self-manage their diabetes care, always leave the *One-Button Bolus* feature disabled to avoid accidental bolus delivery. Enabling the *One-Button Bolus* feature allows for bolus delivery without the use of the twiist app and may result in over delivery of insulin resulting in low blood glucose.

**⚠** If air bubbles are present in the infusion set tubing, perform a cassette change. Air bubbles present in the infusion set tubing may lead to under or over delivery of insulin, which may lead to high or low blood glucose.

 The system is Magnetic Resonance Unsafe. Disconnect your twiist pump before entering an MRI scan room. Do not bring your iPhone or twiist pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner can cause the pump and iPhone to move or lead to electric shocks and may result in severe injury.

**⚠** Always notify medical staff about your diabetes and your twiist automated insulin delivery system. If you need to stop insulin delivery or remove your CGM sensor for a medical procedure, follow your healthcare provider's guidance about insulin missed while disconnected from your pump. Check your blood glucose before disconnection and reconnection and treat your highs and lows.

**⚠** Do not expose your system to:

- X-ray
- Computed Tomography (CT) scan
- Magnetic Resonance Imaging (MRI)
- Positron Emission Tomography (PET) scan
- Diathermy Devices
- Electrocautery Devices
- Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming
- Other exposure to radiation

Remove your twiist system and leave it outside the room prior to these procedures. Failure to do so may lead to harm.

**⚠ Do not expose your system to:**

- Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or programming
- Cardiac Catheterization
- Nuclear Stress Test

Remove your system and leave them outside the room prior to these procedures. Failure to do so may lead to harm.

**⚠ Allow Notifications and Critical Alerts for the twiist app in your iPhone settings.** Failure to allow Notifications and Critical Alerts may lead to missed alert, urgent alert, or alarm notifications which may lead to high or low glucose.

**⚠ Your iPhone should not be used with the twiist automated insulin delivery system if your iPhone:**

- battery cannot last a full day
- shuts down unexpectedly
- cannot be powered down or restarted
- cannot maintain Bluetooth communication
- screen, speaker, camera, or vibration motor are broken

Use of your iPhone under these conditions may result in harm.

**⚠ Avoid using accessibility features on the iPhone.** Using accessibility features on the iPhone may affect the ability to view the twiist app which could lead to harm.

**⚠ Do not use the twiist automated insulin delivery system when using hydroxyurea, a medication used in the treatment of diseases including cancer and sickle cell anemia.** CGM readings being used by the system may be inaccurate while taking hydroxyurea, meaning the twiist automated insulin delivery system will not have accurate information to use for dosage recommendations. This could result in over-delivery of insulin, which can lead to hyperglycemia. Talk to your healthcare provider about using your BG meter for treatment decisions instead.

**⚠** Do not use the twiist automated insulin delivery system if you are taking GLP-1 agonists or SGLT-2 inhibitors, metformin or DPP-4. The twiist automated insulin delivery system has not been tested in populations using additional diabetes medications and the performance of the system in conjunction with these medications is unknown.

**⚠** Avoid using the twiist automated insulin delivery system in oxygen rich environments (greater than 25% oxygen), which includes the use of supplemental oxygen and hyperbaric chambers. Exposure to oxygen rich environments could result in combustion of components of the twiist automated insulin delivery system including your twiist pump and compatible CGM. This can cause severe burns on the body.

**⚠** Do not take external insulin, such as manual insulin injections or inhaled insulins, while Loop is on and the twiist pump is operational. The twiist automated insulin delivery system does not receive information about insulin taken outside the system. If you choose to take additional insulin with another method while Loop is on and the twiist pump is working, over-delivery or under-delivery of insulin may occur, which can lead to high and low glucose. Consult with your healthcare provider about how long to wait after manually taking insulin before enabling automated insulin delivery.

**⚠** Never drive yourself to the emergency room if you need emergency medical care. Ask a friend or family member to take you to the emergency room or call an ambulance.

**⚠** Do not use the twiist automated insulin delivery system if you have a condition which, in the opinion of your healthcare provider, would put you at risk. Examples of individuals who should not use the twiist automated insulin delivery system include those with uncontrolled thyroid disease, renal failure (e.g. dialysis or eGFR <30), hemophilia, or another major bleeding disorder, or unstable cardiovascular disease.

## Cautions

Cautions (**⚠**) provide information about specific scenarios and the possible outcomes that may occur as a result of failing to follow the provided guidance, which may lead to minor or moderate injury.

⚠ Replace your infusion set every 48-72 hours as recommended by your healthcare provider. Wash your hands and use clean technique when filling the cassette, inserting the infusion site, and connecting the infusion set tubing. Failure to do so may lead to infection.

⚠ Make sure the time and date is set correctly on your iPhone. If the time and date is not set correctly, delivery errors may occur resulting in low or high blood glucose.

⚠ *Loop* is not indicated for use by anyone who is pregnant, on dialysis, or critically ill. It is not known how different conditions or medications used in these scenarios may affect performance of the twiist automated insulin delivery system. CGM readings being used by the system may be inaccurate in these cases, meaning the twiist AID system will not have accurate information to use for dosage recommendations. This could result in over-delivery or under-delivery of insulin, which can lead to high or low glucose.

⚠ Check your infusion site every day for proper placement. Replace your infusion site if you notice leaks around the site. Improper placement or leaks around the site may result in under delivery of insulin resulting in high blood glucose.

⚠ Before going to sleep, check to make sure you have enough insulin in your cassette and sufficient charge remaining in your pump battery to last through the night. It is possible to sleep through, or fail to hear, a *Cassette Empty* alarm and miss a portion of your basal delivery.

⚠ Replace pump batteries after four months of use. Failure to replace pump batteries after four months of use may lead to *Cassette Problem* alarms.

⚠ Stop using the pump and switch to your backup insulin delivery method in the event the pump housing is cracked, the pump button is damaged, or there is other evidence of damage to the pump. Failure to do so may lead to pump malfunctions resulting in interruption of therapy.

**⚠ Verify a *One-Button Bolus* by looking at the twiist app to confirm the correct bolus amount. Looking at the twiist app will ensure that you are correctly using the pump button to program the intended bolus.**

**⚠ Only join secure Wi-Fi networks. Unknown or public Wi-Fi networks may not provide data security.**

**⚠ Prolonged noise or vibration may interfere with the pump's ability to continue delivery and trigger an alarm.**

**⚠ Do not use the wall power adapter if it is visibly damaged or malfunctioning. Using a damaged or malfunctioning wall power adapter can result in electrical shock.**

**⚠ Surfaces of the pump battery charger may reach 131 °F (55 °C). When the device is warm to the touch avoid contacting the surfaces. Making contact with the charger while it is warm to the touch may result in burns.**

**⚠ Do not open, crush, heat above 140 °F (60 °C), or incinerate the pump battery. Doing so can lead to fire, burns, and property damage.**

**⚠ Set the volume on your iPhone to be louder than your surroundings so your system notifications can be heard.**

**⚠ Prevent submerging the pump in water for extended periods of time. Keeping the pump submerged in water can block Bluetooth communication between the twiist pump and app, which may cause a delayed response to an alarm condition which may cause under delivery, resulting in high blood glucose.**

**⚠ Federal law restricts this device to sale by or on the order of a licensed physician. Use of this device without the training and supervision of a physician may lead to errors that result in harm.**

**⚠ Do not attempt to open, modify, or repair any parts of the system. Attempting to open, modify, or repair parts of the system could lead to unsafe operation and may lead to harm.**

**!** Contact with insect repellents that contain DEET, skin care products, or sunscreens can damage the pump or cassette, which may lead to leaks, pump malfunctions, or delivery interruption.

Avoid getting insect repellents, skin care products, or sunscreen on the pump or cassette. If these products do get on the cassette or pump, wipe them off immediately with a clean cloth.

**!** Dispose of used components such as cassettes, syringes, needles, infusion sets, and CGM sensors following the instructions from your local authorities. Wash your hands thoroughly after handling used components.

**!** The use of cables other than those provided or specified may result in increased radio frequency emission or decreased radio frequency immunity of the system.

**!** Disconnect your iPhone from audio devices such as Bluetooth headphones or speakers when you are no longer using them. Remaining connected to audio devices when they are no longer in use may lead to missed alert or alarm notifications.

**!** Speak with your healthcare provider about lifestyle changes that may impact your overall insulin needs and settings, such as weight gain or loss or starting or stopping new activities.

**!** Do not expose your twiist pump to X-ray screening used for carry-on and checked luggage. Newer full body scanners used in airport security screening are also a form of X-ray and your pump should not be exposed to them. Notify the security agent that your twiist pump should not be exposed to X-ray machines and request an alternate means of screening. Your pump has been designed to withstand common electromagnetic interference including airport metal detectors.

**⚠ Avoid using the twiist automated insulin delivery system at low atmospheric pressure (below 700hPa).**  
Encounters with low atmospheric pressure can happen at high elevations (above 10,000 feet or 3,048 meters). Exposure to such low atmospheric pressures can damage components of the twiist automated insulin delivery system, including your twiist pump and compatible CGM, which could result in over delivery or under-delivery of insulin, which can lead to low or high blood glucose.

**⚠ Avoid using the twiist automated insulin delivery system in high atmospheric pressure environments (above 1060hPa), which can be found in hyperbaric chambers. Exposure to high atmospheric pressure environments can damage components of the twiist automated insulin delivery system, including your twiist pump and compatible CGM, which could result in over delivery or under-delivery of insulin, which can lead to low or high blood glucose.**

**⚠ Check your glucose frequently during amusement park rides, flying, hiking, skiing, snowboarding or other situations where sudden changes or extremes of air pressure, altitude, or gravity may be occurring. The atmospheric pressure in an airplane cabin can change during flight, which may affect insulin delivery. Rapid changes in altitude and gravity, such as those typically found on amusement park rides or flight take-off and landing, can affect insulin delivery, leading to possible hypoglycemia or injury. If needed, follow your healthcare provider's treatment instructions.**

# CGM Safety Information

The following section includes important safety information related to your CGM. The information presented here does not represent all warnings and cautions related to your CGM. Refer to your CGM manufacturer's instructions for more information on warnings and cautions associated with the use of your CGM.

Additional and repeated warnings and cautions (  or  ) appear throughout this user guide where appropriate.

Taking higher than the maximum dose of paracetamol/acetaminophen (> 1 gram every 6 hours in adults) may affect your Dexcom G6 sensor readings and make them look higher than they really are.

## CGM Warnings

 Do not ignore how you feel or symptoms of high and low glucose. If your CGM glucose readings do not match how you feel, measure your blood glucose with a BG meter even if your CGM is not in the high or low range. Ignoring the symptoms of high and low glucose even when your CGM is not in the high or low range may lead to incorrect treatment decisions which may lead to harm.

When in doubt, get your meter out.

 Do not use a damaged or cracked CGM. Using a damaged or cracked CGM may cause an electrical safety hazard and may prevent your CGM from working correctly.

 Do not ignore CGM wire fractures. A CGM may fracture on rare occasions. If a CGM wire breaks and no portion of it is visible above the skin, do not attempt to remove it. Contact your healthcare provider if you have symptoms of infection or inflammation (redness, swelling, or pain) at the CGM insertion site. If you experience a broken CGM wire, please report this to your CGM manufacturer's Customer Support.

 Dexcom G6 CGM Sensors should be stored between 36 °F (2.2 °C) to 86 °F (30 °C). Do not store your sensors in the freezer. Storing your sensors incorrectly may result in inaccurate readings that may cause you to miss severe low or high blood glucose.

 The Dexcom G6 CGM contains small parts that may be choking hazards. Keep small CGM parts out of the reach of children to prevent injury.

 Dexcom G6 CGM readings, alarms and alerts (provided by your Dexcom G6 app) are not available during the 2-hour sensor warmup period and will not be displayed. Check your blood glucose using your BG meter to prevent severe low or high blood glucose.

 Do not use unapproved CGM insertion sites. Dexcom G6 CGM Sensor insertion in unapproved sites might cause sensor glucose readings to be inaccurate and could result in you missing severe low or high blood glucose.

## CGM Cautions

 Clean your CGM insertion site with alcohol wipes and let your skin dry before inserting the CGM. A dirty insertion site may cause contamination, which may lead to an infection. Not allowing the skin to dry may prevent the transmitter holder from properly sticking.

 Wash your hands before opening the CGM package. Dirty hands may cause contamination of the insertion site, which may lead to an infection.

 Change your CGM insertion site each time you need to insert a new CGM. If you use the same insertion site location too often, it may cause skin irritation or scarring.

 Choose a CGM insertion site that is at least 3 inches (8 cm) away from your insulin infusion site that is unlikely to be bumped, pushed, or slept upon, and is also away from tattoos, scarring or irritation.

 Do not use a CGM if the packaging has been opened or damaged. Use of a CGM from opened or damaged packaging may cause an infection.

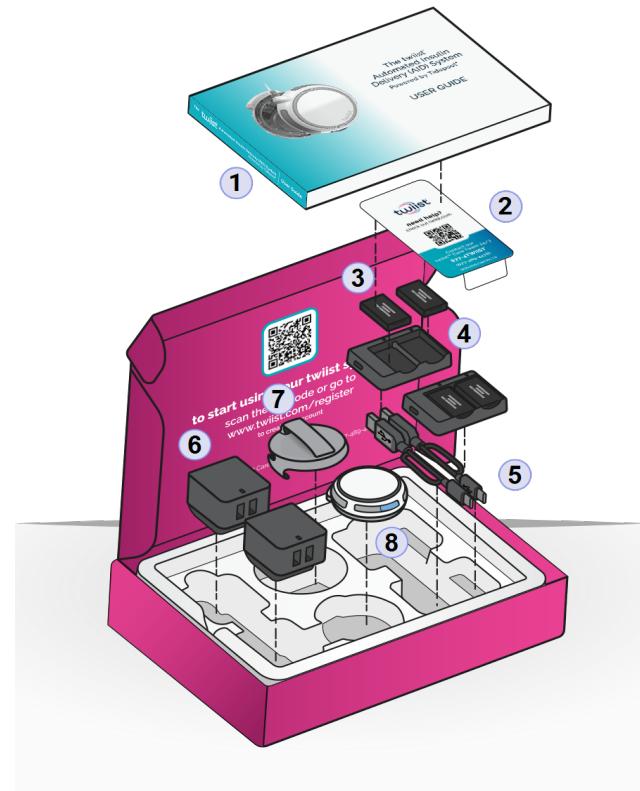
**!** Your CGM and pump should be kept within 20 ft (6 m) of each other without obstructions between them or they may not be able to communicate. To help maintain communication, keep the CGM and pump on the same side of your body. Bluetooth communication does not work well through water. Range may be reduced while swimming or bathing.

# Get to Know your twiist Automated Insulin Delivery System

The twiist automated insulin delivery system starter kit includes:

## Insulin Pump

1. The twiist AID system User Guide
2. QR code to create your account
3. Rechargeable pump battery (4)
4. Pump battery charger (2)
5. USB charging cable (2)
6. Wall power adapter with 2 USB ports (2)
7. Pump clip
8. The twiist pump with attached cover



## Cassettes

The twiist 3 mL cassettes are provided in individual, single-use, sterile packaging. A cassette uses a luer connector to attach to an approved infusion set, and includes a filling port to fill the cassette with insulin.

Cassettes are sterilized using gamma radiation.

- (10) Cassettes

## Needles, Syringes, and Wipes

Additional single-use supplies are necessary to use the twiist automated insulin delivery system and include needles, syringes, and alcohol wipes.

- (10) 3 mL syringes
- (10) 1/2 inch x 26 gauge needles
- (20) Alcohol wipes

## Infusion Sets

- (10) Cleo 90 - 24 inch infusion sets

 Make sure you always have enough cassettes, infusion sets, syringes, and needles to meet your needs.

## Adhesive Patch

The twiist AID system includes disposable adhesive patches that can be used to wear the pump.

- (10) twiist adhesive patches

All CGM components are sold and shipped separately.

When opening the boxes for the first time, check to make sure that all of the listed components are included.

If anything included with the twiist AID system does not work as described, contact your healthcare provider for a replacement.

# Getting Started

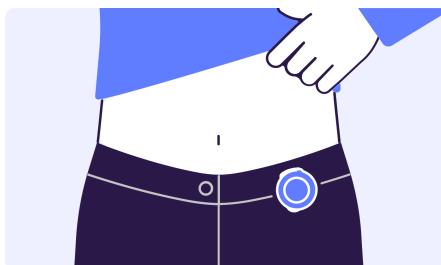
If the pump has been exposed to extremely hot or cold temperatures, allow the pump to sit at room temperature for at least an hour prior to use.

Contact your healthcare provider for assistance with any of the set up instructions.

**A** Do not use the twiist automated insulin delivery system before reading the user guide. Failure to follow the instructions provided in this user guide may result in over or under delivery of insulin, which may lead to low or high blood glucose. If you have questions about appropriate use, contact your healthcare provider or Sequel customer support. *See "Customer Support" on page 195.*

**A** Do not use the twiist automated insulin delivery system if you have not received training on appropriate use by a certified trainer. Discuss your individual training needs with your healthcare provider. Failure to receive the appropriate training could result in serious injury or death.

## The twiist Pump



The twiist pump, when connected to a cassette and infusion set, continuously delivers U-100 fast-acting insulin under the skin at the basal rate(s) (U/hr) set with your healthcare provider. When used with a CGM and the twiist app, basal rates will be adjusted based on your insulin needs.

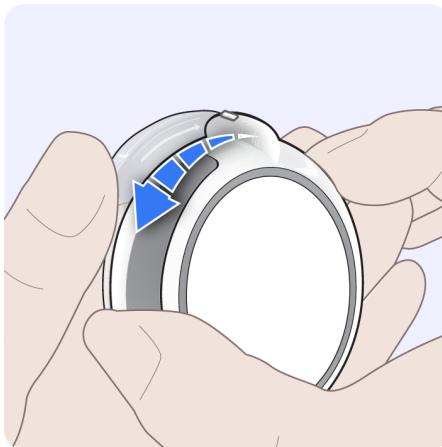
The pump continues to deliver your basal insulin when it is not in communication with the twiist app.

The twiist pump is also used to deliver a bolus of fast-acting insulin to cover carbs or bring high glucose down into your *Correction Range*.

The pump is powered by a rechargeable battery designed for the twiist AID system. During a *Cassette Change*, which occurs at least every 3 days, the battery is removed from the pump and charged. A fully charged battery is inserted into the pump.



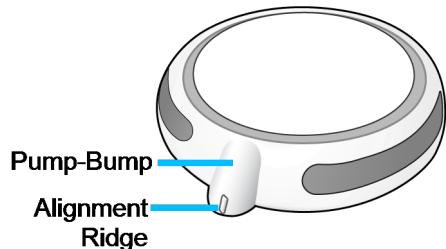
The twiist pump is shipped with an attached cover. The cover is removed and a cassette is attached and filled during setup with your certified twiist trainer. When the cover is not in use, store it in a safe, easily accessible location along with this user guide and your other system accessories.



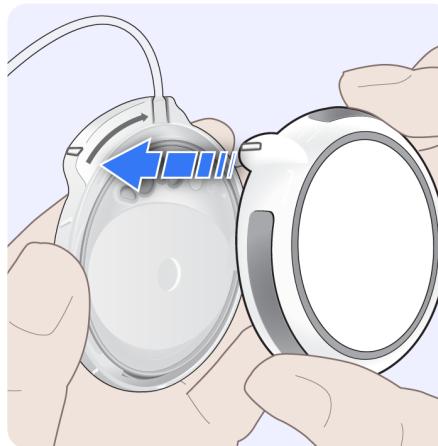
When the pump is not in use, store the pump with the cover attached.

## Pump-Bump

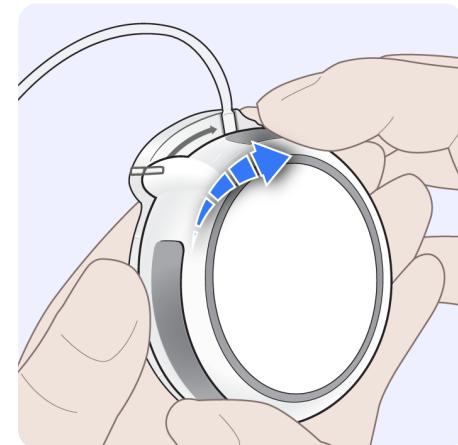
The *pump-bump* and alignment ridge are features on the pump to help align the cassette and pump when a cassette is being attached to the pump.



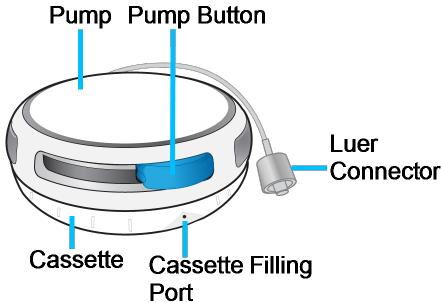
When attaching a new cassette to the pump, align the ridge on top of the *pump-bump* with the ridge on the cassette. When the ridges are aligned, turn the pump clockwise toward the infusion set tubing.



When the ridge on the *pump-bump* is aligned with the infusion set tubing, the cassette has been fully attached.



## Pump Button



The pump button provides the ability to:

- Confirm that delivery is in progress
- Resume insulin delivery
- Place the pump into pairing mode (when not connected to a cassette).
- Deliver a *One-Button Bolus*

Press and hold the **pump button** for 3 seconds to resume delivery or confirm that delivery is in progress. The *Delivering* sounds will be played by the pump to let you know that delivery is in progress.

The pump button is used to place the pump into pairing mode, in the event that it needs to be paired with the twiist app again. [See "Pair Your Existing Pump" on page 103.](#)

The pump button can be used to deliver a *One-Button Bolus* (when enabled). [See "One-Button Bolus" on page 131.](#)

## How to Wear your twiist Pump

Your twiist pump can be attached to a belt or clothing with the provided pump clip. The twiist adhesive patches can be used to attach the pump to the body. The pump can also be placed in a clothing pocket.

In order to maximize the signal between your pump and CGM, and minimize communication interruptions, your pump and CGM should be placed on the same side of your body. The twiist logo on the pump should face away from your body.

Make sure to secure the infusion set tubing and pump to prevent it from catching on other objects.

 Avoid strong magnetic fields.  
Strong magnetic fields can trigger the latch detect sensor within the pump causing a false *Cassette Not Attached* alarm.

 When the system is used in a loud environment your iPhone should be kept in a clothing pocket so alarm vibration can be felt. Check the twiist app for alarms and alerts if you are in an environment where you cannot feel vibration or hear the system sounds.

 Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery error and lead to serious injury.

 Pets may damage your infusion set tubing while sleeping which may lead to an interruption of medication delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.

### Pump Clip



1. The pump slides into the pump clip with the pump-bump facing up.

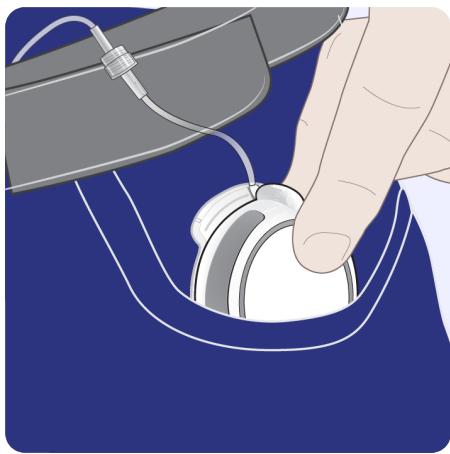
2. Clip to a belt or clothing, where the pump can be firmly supported.

### Adhesive Patch



1. Peel the backing off the adhesive patch.
2. Apply the patch to your body.
3. Insert the pump into the clip on the adhesive patch.

## *In Your Pocket*



Insert the pump into your pocket  
making sure the infusion set tubing  
is not pinched.

## System Sounds

Your iPhone and the twiist pump play sounds in order to help you identify the current status of the system.

The twiist app alert, urgent alert, and alarm audio and vibration are controlled through the settings on your iPhone.

If the volume is turned down, or your iPhone is silenced, audio notifications played on your iPhone may be delayed.

|                |   |
|----------------|---|
| One quick beep | The pump battery has been inserted into the pump. |
|                | The pump button has been pressed.                 |
| <i>Ready</i>   |   |
| One beep       | Ready to progress to the next step.               |

|                    |   |
|--------------------|---|
| One repeating beep | The pump is busy. Wait until the pump is ready.                                 |
|                    | When priming the cassette and infusion set tubing, you will need to stop prime. |

Table 1: System Sounds

### Pump Battery and Button

Table 1: System Sounds

| <i>Delivering</i>       |   |
|-------------------------|---|
| Three ascending tones   | The pump is delivering insulin.                     |
|                         | A change to your basal rate settings has been made. |
|                         | Bolus delivery has been started or stopped.         |
| <i>Delivery Stopped</i> |   |
| Four descending tones   | Insulin delivery has been suspended.                |

| <i>Alert</i>  |   |
|---|---|
| Two beeps   | The twiist pump is in an alert status. Check the alert displayed on the twiist app for additional information.                                |
| <i>Urgent Alert</i>   |   |
| Three beeps   | The twiist pump is in an urgent alert status. Check the alert displayed on your twiist app for additional information.                        |
| <i>Alarm</i>  |   |
| Three beeps + two beeps (2 times), repeating every 10 seconds | The twiist pump is in an alarm status and is not delivering insulin. Check the alarm displayed on your twiist app for additional information. |

Table 1: System Sounds

| <i>One-Button Bolus</i>                    |  |
|--|--|
| Ascending beeps for each pump button press | Programming a <i>One-Button Bolus</i> .  |
| <i>One-Button Bolus Canceled</i>           |  |
| One extended tone                          | Programming a <i>One-Button Bolus</i> was not successful. This can occur if the <i>One-Button Bolus</i> is not confirmed within 10 seconds of the bolus request. |

## Charge the Pump Batteries

Before you use your twiist automated insulin delivery system, and each time you replace your cassette and infusion set, make sure you charge the pump batteries.

If the pump batteries have been exposed to extremely hot or cold temperatures, allow them to cool off/warm up for 20 minutes before charging.

The pump batteries typically take 6 hours or less to charge.

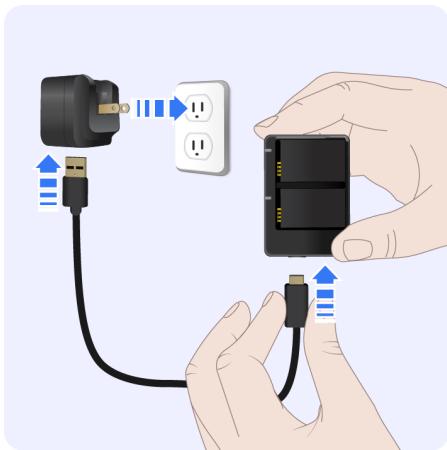
The pump batteries should be charged using the provided battery charger and wall power adapter.

Keep the pump batteries, pump battery charger, and wall power adapter clean and dry.

A fully charged pump battery will power the pump for 3 days (72 hours) and should be swapped each time a cassette change is completed.

### To charge the pump batteries:

1. Plug the USB cable into the wall power adapter and the battery charger.
2. Plug the wall power adapter into a wall power outlet.



3. Insert the pump batteries into the battery charger by aligning the contacts on the batteries with the contacts on the charger.



 Avoid touching the electrical contacts on the battery charger when the charger is connected to a power source.

The pump battery charger status light color indicates the following:

- Green - The pump battery is fully charged and ready for use.
- Orange - The pump battery is charging.

- Blinking Red - Charging fault. The pump battery is not charging as expected.

## Continuous Glucose Monitoring (CGM)



The Dexcom G6® Continuous Glucose Monitoring (CGM) system is a disposable medical device that is inserted under the skin to continuously monitor glucose levels for up to ten days.

The CGM sends readings through a Bluetooth connection, to the twiist pump and Dexcom G6 application every 5 minutes.

The Dexcom G6 communicates with both the twiist pump and the Dexcom G6 CGM app on your iPhone at the same time. The twiist app displays sensor glucose readings and trend information.

The Dexcom G6 app should be used to manage your Dexcom G6 CGM, including your CGM alerts.

For more detailed instructions and important safety information, refer to instructions included with your Dexcom G6.

If you are using a Dexcom G6 CGM, set it up using the Dexcom G6 app prior to getting started with twiist automated insulin delivery system.

 Use the Dexcom G6 CGM app to manage your CGM. The twiist app does not replace the Dexcom G6 CGM app.

## The twiist App



The twiist app displays information from your Bluetooth connected diabetes devices, including insulin data from your twiist automated insulin delivery system and glucose information from your CGM.

In order to use the twiist app, you need to have an iPhone capable of:

- Establishing and maintaining a Bluetooth connection
- Providing audio and vibration feedback

- Maintaining basic operation of the display and touchscreen
- Maintaining sufficient charge between charging

 It is recommended to charge your iPhone daily to ensure you always have access to the twiist app.

Before using the twiist app the following must be understood:

- The iPhone passcode feature must be enabled in order to use the twiist app.
- Your iPhone, running the twiist app, should be kept with you at all times while using the twiist automated insulin delivery system. Insulin delivery will continue when your iPhone is not present.
- In order to hear or feel notifications, the iPhone volume must be turned up and vibrate must be enabled.